

- 1 1. (Original) A water dispersible tablet formulation comprising an active ingredient as
2 beta lactam antibiotic and optionally a beta lactamase inhibitor, a disintegrating agent,
3 said disintegrating agent being used both intragrularly and extragrularly, and
4 pharmaceutically accepted excipients.
- 1 2. (Original) The formulation of claim 1 wherein said β -lactam antibiotic is selected
2 from the group consisting of penicillin, cephalosporin and carbapenam.
- 1 3. (Original) The formulation of claim 1 wherein said penicillin is amoxicillin, said
2 cephalosporins is cefuroxime axetil, cefpodoxime proxetil or cefalexin and said
3 carbapenam is loracarbef or imipenem.
- 1 4. (Original) The formulation of claim 1 comprising the disintegrant selected from the
2 group consisting of croscarmellose sodium, polyvinylpyrrolidone and sodium starch
3 glycolate.
- 1 5. (Currently Amended) The formulation of claim 1 ~~or 4~~ comprising about 1 % to about
2 2.5 % w/w of an ~~the~~ intragrular disintegrant.
- 1 6. (Currently Amended) The formulation of claim 1 ~~or 4~~ comprising about 1 % to about
2 5 % w/w of an ~~the~~ extragrular disintegrant.
- 1 7. (Currently Amended) The formulation of claim 1 comprising a ~~the~~ filler selected from
2 the group consisting of lactose, microcrystalline cellulose and starch.
- 1 8. (Currently Amended) The formulation of claim 1 further ~~or 7~~ comprising 40-70 %
2 w/w of a ~~the~~ said filler.
- 1 9. (Original) The formulation of claim 1 comprising the lubricants selected from the
2 group consisting of talc, magnesium stearate, stearic acid and colloidal silicon
3 dioxide.

1 10. (Original) The formulation of claim 1 wherein said dispersible tablet has a
2 disintegration time of less than one minute.

1 11. (Currently Amended) The formulation of claim 1 wherein said tablets form
2 suspension after incorporating in aqueous mediawater.

1 12. (Original) The formulation of claim 11 wherein said suspension formed completely
2 passes through a 750 μm sieve.

1 13. (Original) The formulation of claim 1 wherein said beta lactamase inhibitor is
2 clavulanic acid or a salt thereof.

1 14. (Original) The formulation of claim 13 wherein the clavulanic acid salt is potassium
2 clavulanate.

1 15. (Currently Amended) The formulation of claim ~~13 or 14~~ wherein the ratio of
2 amoxicillin to potassium clavulanate is 12:1 to 1:1.

1 16. (Original) The formulation of claim 15 wherein the ratio of amoxicillin to potassium
2 clavulanate is 7:1.

1 17. (Currently Amended) The formulation of claim ~~1 or 11~~ wherein the tablet when
2 dispersed in an aqueous media, has a particle size distribution of d90 less than 600
3 μm .

1 18. (Currently Amended) The formulation of claim ~~1 or 11~~ wherein the tablet when
2 dispersed in an aqueous media, has a particle size distribution of d90 less than 400
3 μm .

1 19. (Currently Amended) The formulation of claim ~~1 or 11~~ wherein the tablet when
2 dispersed in an aqueous media, has a particle size distribution of d50 less than 300
3 μm .

1 20. (Currently Amended) A process for the preparation of a dispersible tablet comprising
2 a beta lactam antibiotic, an optional beta lactamase inhibitor and an intragrangular
3 disintegrant, said the process comprising: aqueous granulating of a beta lactam
4 antibiotic, an optional beta lactamase inhibitor and an said intragrangular disintegrant
5 incorporated either in the dry mix or the granulating fluid, are aqueous granulated,
6 dried, mixed; drying the granulation; missing the dried granulation with the
7 extragrangular disintegrant, a filler, a flavour, a lubricating agent, and a sweetener; and
8 compressing the resulting blend is compressed to into tablets.

1 21. (Currently Amended) The process of claim 20 wherein the tablet
2 comprisingcomprises 30-50 % w/w amoxicillin.

1 22. (Currently Amended) The process of claim 20-~~or~~-21 wherein the amoxicillin has a
2 particle size of d_{90} less than 150 μm .

1 23. (Currently Amended) The process of claim 20-~~or~~-21 wherein the amoxicillin has a
2 particle size of d_{90} less than 75 μm .

1 24. (Currently Amended) The process of claim 20-~~or~~-24 wherein the tablet comprising
2 comprises about 1 % to about 2.5 % w/w of intragrangular disintegrant.

1 25. (Currently Amended) The process of claim 20-~~or~~-24 wherein the tablet comprising
2 comprises about 1 % to about 5 % w/w of extragrangular disintegrant.

1 26. (Original) The process of claim 24-~~or~~-25 wherein the disintegrant is selected from the
2 group consisting of croscarmellose sodium, polyvinylpyrrolidone and sodium starch
3 glycolate.

1 27. (New) The process of claim 25 wherein the disintegrant is selected from the group
2 consisting of croscarmellose sodium, polyvinylpyrrolidone and sodium starch
3 glycolate.

4 28. Cancelled.

1 29. Cancelled.

1 30. Cancelled.

1 31. (Original) The process of claim 20 wherein said granules are dried to an equilibrium
2 relative humidity of less than at 40% at a bed temperature of not more than 60°C.

1 32. (Currently Amended) The process of claim ~~20~~²⁸ wherein said granules are dried to an
2 equilibrium relative humidity of less than 25% at a bed temperature of not more than
3 50°C.

1 33. (Original) The process of claim 20 wherein said dispersible tablet has a disintegration
2 time of less than one minute.

1 34. (Currently Amended) The process of claim 20 wherein the e~~comprising~~-beta lactamase
2 inhibitor is as-clavulanic acid or a salt thereof, and the beta lactam antibiotic is as
3 amoxicillin.

1 35. (Currently Amended) The process of claim ~~33-31~~ wherein the clavulanic acid salt is
2 potassium clavulanate.

1 36. (Currently Amended) The process of claim ~~33-31~~ or ~~34~~³² wherein the ratio of
2 amoxicillin to potassium clavulanate is 12:1 to 1:1.

1 37. (Currently Amended) The process of claim ~~35-33~~ wherein the ratio of amoxicillin to
2 potassium clavulanate is 7:1.

1 38. (Original) The process of claim 20 wherein the tablet when dispersed in an aqueous
2 media, has a particle size distribution of d90 less than 600 µm.

1 39. (Original) The process of claim 20 wherein the tablet when dispersed in an aqueous
2 media, has a particle size distribution of d90 less than 400 µm.

1 40. (Original) The process of claim 20 wherein the tablet when dispersed in an aqueous
2 media, has a particle size distribution of d50 less than 300 μm .

1 41. (Currently Amended) A process for the preparation of a water-dispersible tablet
2 formulation, the process comprising:
3 aqueous granulation of a β -lactam antibiotic and an intragraniular disintegrant,
4 incorporated either in the dry mix or in the granulating fluid;
5 drying the granulated mixture;
6 mixing the dried granules with optional extragraniular disintegrants, fillers,
7 flavours, sweeteners, or lubricating agents; and ~~comprising~~ compressing the
8 resulting blend to form water-dispersible tablets.

1 42. (Currently Amended) The process of claim 4038, wherein the β -lactam antibiotic is
2 selected from penicillins; cephalosporins; and carbapenems.

1 43. (Currently Amended) The process of claim 4038, wherein the β -lactam antibiotic is
2 amoxicillin.

1 44. (Currently Amended) The process of claim 4038, wherein the disintegrant is selected
2 from croscarmellose sodium, polyvinylpyrrolidone, and sodium starch glycolate.

1 45. (Currently Amended) The process of claim 4341, wherein the intragraniular
2 disintegrant is croscarmellose sodium.

1 46. (Currently Amended) The process of claim 4341, wherein the disintegrant is present
2 intragraniularly at a concentration of about 1 % to about 2.5 % w/w of the tablet
3 formulation.

1 47. Cancelled.

1 48. Cancelled.

1 49. Cancelled.

1 50. Cancelled.

1 51. Cancelled.

1 52. Cancelled.

1 53. (Currently Amended) The process of claim 4038, wherein the suspension formed
2 upon dispersion can completely pass through a 750 μm sieve.

1 54. A process for the preparation of a stable amoxicillin dispersible tablet formulation,
2 ~~wherein amoxicillin and intragranular disintegrant, incorporated either in the dry mix~~
3 ~~or in the granulating fluid the process comprising: granulation of amoxicillin and~~
4 ~~intragranular disintegrant; drying the granulated mixture; mixing the dried granules~~
5 ~~with optional extragranular disintegrants, fillers, flavours, sweeteners, or lubricating~~
6 ~~agents; and comprising compressing the resulting blend to form water-dispersible~~
7 ~~tablets, wherein amoxicillin and intragranular disintegrant are incorporated either in~~
8 ~~the dry mix or in the granulating fluid.~~

1 55. (Currently Amended) The process of claim 5345, wherein amoxicillin comprises
2 about 30 to about 50 % w/w of the formulation.

1 56. (Currently Amended) The process of claim 5345, wherein amoxicillin has a particle
2 size of d_{90} less than about 150 μm .

1 57. (Currently Amended) The process of claim 5345, wherein amoxicillin has a particle
2 size of d_{90} less than about 75 μm .

1 58. Cancelled.

1 59. Cancelled.

1 60. Cancelled.

1 61. Cancelled.

1 62. Cancelled.

1 63. Cancelled.

1 64. Cancelled.

1 65. Cancelled.

1 66. (Currently Amended) The process of claim 5345, wherein the granules are dried to an
2 equilibrium relative humidity of less than about 40% at a bed temperature of not more
3 than about 60°C.

1 67. (Currently Amended) The process of claim 6545, wherein the granules are preferably
2 dried to an equilibrium relative humidity of less than about 25% at a bed temperature
3 of not more than about 50°C.

1 68. Cancelled.

1 69. Cancelled.

1 70. Cancelled.

1 71. Cancelled.

1 72. Cancelled.

1 73. Cancelled.

1 74. (Currently Amended) ~~The A-process of claim 45 for the preparation of a water-~~
2 ~~dispersible tablet formulation~~ wherein the tablet when dispersed in an aqueous media,
3 has a particle size distribution of d90 less than 600 μm .

1 75. (Currently Amended) The process of claim 7351, wherein the d90 is less than about
2 400 μm .

1 77. (Currently Amended) The A-process of claim 45 for the preparation of a stable,
2 dispersible tablet formulation of amoxicillin, and intragranular disintegrant,
3 incorporated either in the dry mix or in the granulating fluid; drying the granulated
4 mixture; mixing the dried granules with optional extragranular disintegrants, fillers,
5 flavours, sweeteners, or lubricating agents; and comprising the resulting blend to
6 form water-dispersible tablets, wherein the tablet is bioequivalent to the amoxicillin
7 suspension formulation available commercially under the trade name Amoxil™ as
8 required by the USFDA.